

REMARKS

In response to the final Office Action dated August 11, 2005, Applicants have amended the claims, which when considered with the following remarks, is deemed to place the present application in condition for allowance, or, alternatively, in better condition for appeal. Favorable consideration of all pending claims is respectfully requested.

In the Office Action of August 11, 2005, the Examiner has maintained the rejection of claims 2, 5, 7, 11, 14, 17, 21, 25, 27, 30, 36, 54 and 55, and claims 8-10, 24, 37-41, 43-45, 47-50, 56 and 57 dependent thereon, as allegedly violative of the written description requirement of 35 U.S.C. § 112, first paragraph, since “neither the specification nor the prior art describe plant CKIs that comprise 2 to 3 unspecified amino acids at any unspecified position in each motif...since peptides that are at least 70% identical to SEQ ID NOs: 34-39 would be expected to have 2 to 3 amino acids substituted at varying positions in SEQ ID NOs:34-39.” *See* Office Action, page 9, first full paragraph. Thus, although literal support for the language “an amino acid sequence that is at least 70% identical thereto” exists in the specification (*see* pages 54-55 of the specification), the Examiner’s position is that exemplified ICK sequences in the specification and prior art appear to have only one substitution.

In response to the rejection and in order to advance prosecution in this case, Applicants have amended claims 2, 5, 7, 11, 14, 17, 21, 25, 27, 30, 36, 54 and 55 to recite the percent identities exemplified by different plants as set forth in Table 2 of the specification. Thus, in those cases where the plant ICKs listed in Table 2 do not have a motif which exactly matches that found in SEQ ID NO:34 or 35, there is a one out of 8

amino acid sequence identity, i.e., 87.5% sequence identity. Similarly, in those cases where the plant ICKs listed in Table 2 do not have a motif which exactly matches that found in SEQ ID NO:36, there is one out of ten amino acid sequence identity, i.e., 90% identity. Claims 7, 11, 14, 17, 21, 25, 27, 30, 36, 54 and 55 have thus been amended to reflect the same.

With respect to claims 54 and 55, Table 2 reflects various plant ICKs having 87.5% identity to SEQ ID NO:37; 100% identity to SEQ ID NO:38, and 75% identity to SEQ ID NO:39. Accordingly, claims 54 and 55 have been amended to recite these sequence identities.

It is respectfully submitted that the language “an amino acid sequence that is at least 87.5% identical thereto” and “an amino acid sequence that is at least 90% identical thereto”, as presently recited in the claims although not found in the specification *ipsis verbis*, certainly falls in the range of “at least 70% identical thereto” which language is found *ipsis verbis* in the specification (*see* pages 54-55 of the specification). Moreover, the teachings of the specification provide written description support for “having at least 87.5% identity thereto” and “at least 90% identity thereto” since e.g., Table 2 specifically lists nine different plant ICKs with consensus sequences having at least 87.5 % identity to SEQ ID NO:34 and SEQ ID NO:35 and having at least 90% identity to SEQ ID NO:36.

Thus, the record reflects that the position of the Examiner throughout examination of the present application has been that Applicants are not entitled to the language “at least 70% identity thereto” which language finds literal support in the specification (*see* pages 54-55 of specification) because such language is a “mere assertion” in view of the fact that neither the specification nor the prior art describe plant CKIs comprising 2 to 3

unspecified amino acids at any unspecified position since peptides that are at least 70% identical to SEQ ID NOs:34-39 would be expected to have 2 to 3 amino acids substituted at varying positions in SEQ ID NOs:34-39.

As presently amended, the claims recite the exact sequence identities, i.e., at least 87.5% and at least 90% identity, disclosed by the specification for nine different plant ICKs. These exact sequence identities fall within the range of "at least 70% identity." That is, one skilled in the art having Table 2 in hand along with the remaining teachings of the specification and the literature extant at the time the application was first filed, would observe that the motifs of various ICKs listed in Table 2 do not match the consensus sequences perfectly, unless one amino acid substitution is taken into account, i.e., one out of eight amino acids of SEQ ID NOs: 34 and 35 (at least 87.5% identity), and one out of 10 amino acids of SEQ ID NO:36 (at least 90% identity).

The specification of the application provides a written description of the genus of plant CKIs "sufficient to distinguish it from other materials." *See University of California v. Eli Lilly and Co.* 119 F3d 1559, 1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997). Claims 2, 5, 7, 11, 14, 17, 21, 25, 27, 30, 36, 54 and 55, and claims 8-10, 24, 37-41, 43-45, 47-50, 56 and 57 dependent thereon, presently recite this genus. Withdrawal of the rejection of these claims under the written description requirement of 35 U.S.C. § 112, first paragraph is therefore warranted.

Claims 60-92 have been rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. As indicated on pages 2-3 of the Office Action, it is the position of the Examiner that claims 60-92 contain subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, the Examiner has objected to the recitation of “wherein the CKI comprises the amino acid sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36, wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one amino acid substitution therein.” According to the Examiner, this limitation allegedly does not find support in the specification and therefore allegedly constitutes new matter. Office Action, page 2. Claims 89-90 recite “wherein the CKI further comprises the consensus sequences set forth in SEQ ID NO: 37, SEQ ID NO:38 and SEQ ID NO:39, wherein any one of the sequences set forth in SEQ ID NOs:37-39 may have one amino acid substitution therein” and are also rejected as allegedly not supported by the specification and allegedly constituting new matter. Office Action, page 3.

As set forth on page 4 of the office action, the Examiner acknowledges Applicants’ position that the motifs having the amino acid sequence set forth in SEQ ID NOs:34-39 do not in some cases, cover the motifs as they appear in the different CKIs unless a specific amino acid substitution is taken into account. According to the Examiner however, such an observation allegedly does not support a description of the claimed genus recited in “wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one amino acid substitution therein” since this language allows for an unspecified amino acid substitution at any position in each sequence.

On page 10 of the office action, the Examiner takes the position that Applicants' reliance on *Ex parte Yuejin Sun* is inappropriate, since the opinion in support of the decision was not written for publication and is not binding precedent of the Board. Applicants submit that since the previous paper was an amendment, and not an appeal brief, it is certainly not inappropriate to mention this case. Referencing this case as well as providing a copy as Exhibit A was done as a courtesy in order to direct the Examiner to a case in the same field of technology, where one particular panel of the Board of Appeals and Patent Interferences might not agree with the position the Examiner has taken in the present application.

On page 10 of the Final Office Action, the Examiner has now characterized the statement in the previous office action, dated October 29, 2004. page 5, last line, to page 6, line 2, that "one skilled in the art would not know on the basis of the disclosure which of the 20 different amino acid residues would occupy which of the eight of ten available positions in each of the recited motifs that plant CKIs comprise" as having less to do with "predictability" and more to do with "visualization."

For the record, Applicants do not agree with the Examiner's characterization that one skilled in the art would not know on the basis of the disclosure which of the 20 different amino acid residues would occupy which of the eight of ten available positions in each of the recited motifs that plant CKIs comprise. A more accurate characterization has been provided many times by Applicants during prosecution of this application: one skilled in the art, having the present specification in hand at the time the application was first filed, would have reasonably understood that the plant CKIs listed in Table 2 and comprising the consensus sequences also set forth in Table 2 as SEQ ID NOs:34-39,

often have an amino acid substitution in one or more of these sequences. Thus, the substitution would only occur in *one* position and would not be an undeterminable substitution, but a very well defined one, one out of a possible twenty known amino acids. Whether characterized as having to do with “predictability” or “visualization”, such a substitution is not fatal to a sufficient written description under the statute.

The Examiner has erred by dismissing the declaration of Dr. Bergounioux without an adequate explanation of how the declaration failed to overcome a *prima facie* case that the pending claims are not supported by the written description. The *only* comments the Examiner has provided with respect to the Bergounioux declaration is an insistence that “sequences described after the filing date of the instant application (May 18, 2000) cannot be used to support a description of the claimed sequence” (Office Action page 16) and “in the instant case using the consensus sequences as well as other teachings provided by the present application to make and use other undisclosed plant ICKS does not describe other undisclosed plant ICKS” (Office Action, page 18). Applicants have responded to this position of the Examiner with respect to the previously filed Van Camp Rule 132 declaration -- the fact that a sequence was published after the filing date of the present invention, does not take away from the declarant’s relying on the written description of the present application in identifying that sequence and using the same in the presently claimed method. Nor does the fact that a sequence was published after the filing date of the present application take away from the fact that in relying on the written description in identifying this later-published sequence, the declarant reasonably believed that the inventors of the present application invented i.e., had possession of the subject matter later claimed by them

It is to this issue that *In re Hogan*, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977) was first cited by Applicants. Thus, while it is true that a later dated disclosure cannot supplement an insufficient disclosure in a prior dated application, the use of later publications (in this case, the later disclosures of rice CKI ICK2 submitted as part of the van Camp Rule 132 declaration and the later disclosure of tobacco CKI KIS1a as part of the Bergounioux Rule 132 declaration) as evidence of the state of the art existing on the filing date of the application is appropriate. *See e.g. In re Hogan, Id* at 605, 194 USPQ at 537. The fact that Hogan involved an enablement rejection rather than a written description rejection is not relevant to the genuine issue in the present application: the state of art as of the filing date of the present application and what a skilled artisan would have reasonably believed at that time. Such issue *was* addressed in the Bergounioux declaration, but was dismissed by the Examiner with respect to the written description requirement.

The declaration of Dr. Bergounioux goes to the matter of what a reasonable skilled artisan believed the inventors had in their possession as of the filing date of the present application, *as evidenced by a skilled artisan's reasonable reliance thereon*. The post-filing date CKI sequence provided by Dr. Bergounioux evidences the reasonableness of her belief and reliance.

The U.S. PTO bears the initial burden of presenting a prima facie case of unpatentability. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). With respect to the written description requirement, that burden is discharged by “presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d

257, 263, 191 USPQ 90, 97. The burden placed on the examiner varies, depending on what the applicant claims. Where an applicant claims embodiments of the invention that are completely outside the scope of the specification, then the examiner or Board need only establish this fact to make out a *prima facie* case. *Id* at 263-64, 191 USPQ at 97.

Where as here, the specification provides a description of the claimed invention, albeit not in *ipsis verbis*, then the Examiner or Board, in order to meet the burden of proof, must provide reasons why one of ordinary skill in the art would not consider the description sufficient. *See* 541 F2d at 264, 191 USPQ at 98, cited with approval in *In re Alton* 76 F3d 1168, 1175, 37 USPQ 2d 1578, 1583 (Fed Cir. 1996). The burden of coming forward with evidence or argument then shifts to the applicant. 977 F.2d at 1445, 24 USPQ2d at 1444.

In order to overcome a *prima facie* case of insufficient written description, an applicant must show that the invention as claimed is adequately described to one skilled in the art. “After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of the evidence with due consideration to persuasiveness of argument.” 977 F2d at 1445, 24 USPQ2d at 1444.

In *Alton*, after a claim was first rejected under section 112, first paragraph, the applicant submitted evidence to rebut the rejection in the form of a declaration. This declaration (“the Wall declaration”) contained statements of fact directly addressing the issue of whether the specification adequately described the subject matter recited in the rejected claim. The Wall declaration set forth facts which supported the position that one of ordinary skill in the art would have understood the inventor (*Alton*) to be in

possession of the claimed subject matter as of the relevant date. The Examiner's response to the Wall declaration was dismissive, stating that "the specification must describe the precise analog claimed."

The Court of Appeals for the Federal Circuit held the Examiner in error for several reasons. Most relevant to the issues in the present application, the court opined:

The Wall declaration addresses why the claimed subject matter, although not identical to the analog described in the specification, was in Alton's possession. The statement in the examiner's answer that the number of possible analogs encompassed by the specification is substantial does not rebut the thrust of the Wall declaration because the Wall declaration explains why one of ordinary skill in the art would have realized that Alton had possession of one particular analog. In sum, in his final rejection and again in his Answer, the examiner dismissed the Wall declaration and provided only conclusory statements as to why the declaration did not show that a person of skill in the art would realize that Alton had possession of the claimed subject matter in 1983.

Id. at 1176, 37 USPQ2d at 1584.

In the present application, by stating "[t]he Examiner maintains that the sequences described after the filing date of the instant application (May 18, 2000) cannot be used to support a description of the claimed sequences" Office Action page 16, and "in the instant case using the consensus sequences as well as other teachings provided by the present application to make and use other undisclosed plant ICKS does not describe other undisclosed plant ICKS", (Office Action, page 18), the Examiner has failed to articulate adequate reasons to rebut the Bergounioux declaration with respect to the written description rejection.

In particular, the Examiner has failed to address Dr. Bergounioux's statements such as paragraph 9 and part of paragraph 10 reproduced below:

9. The consensus sequences shown in Table 2 of the present application vary somewhat from plant species to plant species. It is also my considered scientific opinion however, that one skilled in the art would recognize that even if the consensus sequences vary somewhat from plant to plant, a motif in a plant having about 70% identity (or one amino acid substitution) to the consensus sequences set forth in Table 2 (SEQ ID NOs:34-39), would be reasonably expected to function in the claimed invention with predictable results. Indeed, this is just what we have shown in our publication provided at Exhibit B with the results obtained from transformed 35S::NtKIS1a plants.

10. The foregoing paragraphs form the basis for my recognizing from the disclosure of the above-identified application, that Lieven DeVeylder et al., the applicants of the above-identified application, invented the presently claimed subject matter including the limitations recited therein, as of its filing date.

Under *Alton*, by failing to articulate adequate reasons to rebut the Bergounioux declaration with respect to sufficiency of written description, the Examiner has failed to consider the totality of the record for the purpose of issuing a final rejection and has thus erred as a matter of law.

Sufficiency of written description under 35 U.S.C. 112, first paragraph, was most recently examined by the Federal circuit in *Capon v. Eshhar*, 418 F.3d 1349, 76 USPQ 1078 (Fed. Cir. 2005). Addressing the PTO's concerns that for biochemical processes relating to gene modification, protein expression, and immune response, success is not assured, the court opined:

However, generic inventions are not thereby invalid.
Precedent distinguishes among generic inventions that are

adequately supported, those that are merely a “wish” or “plan”, the words of *Fiers v. Revel*, 984 F.2d at 1171, and those in between, as illustrated by *Noelle v. Lederman*, 355 F.3d at 1350; the facts of the specific case must be evaluated. The Board did not discuss the generic concept that both Capon and Eshhar described – the concept of selecting and combining a gene sequence encoding the variable domain of an antibody and a sequence encoding a lymphocyte activation protein, into a single DNA sequence which, upon expression, allows for immune responses that do not occur in nature. *The record does not show this concept to be in the prior art, and includes experimental verification as well as potential variability in this concept.*

Id. at F.3d 1360, 76 USPQ at 1086, *emphasis added*.

As in *Capon v. Eshhar*, the Examiner here has not considered the generic concept that Applicants of the present application have described, i.e., the concept of identifying and using a plant CKI in order to affect various phenotypic traits in plants. Also as in *Capon v. Eshhar*, the record in the present application does not show this concept to be in the prior art, and includes experimental verification as well as potential variability in the concept (provided by the specification, previously submitted declarations, and post-filing date publications).

While it is necessary that an applicant for a patent give to the public a complete and adequate disclosure in return for the patent grant, the *certainty* required of the disclosure is not greater than that which is *reasonable*, having due regard to the subject matter involved. *In re Storrs*, 245 F.2d 474, 478 (CCPA 1957), *cited with approval in Capon v. Eshhar*, 418 F.3d 1349, 1360, 76 USPQ 1078, 1087, *emphasis added*. The prior art teaches various CKI amino acid sequences. The specification of the present invention teaches one how to identify additional plant CKIs using the consensus sequences first provided by the present application and also teaches that a plant CKI for use in the

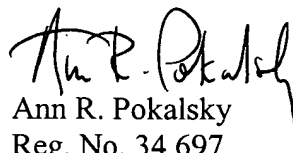
method claims of present invention may have one amino acid substitution in a consensus sequence, or may exhibit at least 70% sequence identity to such consensus sequences, e.g., at least 87.5% or at least 90%. In stating that “using the consensus sequences as well as other teachings provided by the present application to make and use other undisclosed plant ICKS does not describe other undisclosed plant ICKS” (Office Action, page 18, lines 1-3), the Examiner is demanding a certainty of disclosure which is unreasonable, having due regard to the subject matter involved, and when the specification and the record is considered as a whole.

For the forgoing reasons, Applicants request withdrawal of the rejection of claims 60-92 as well as claims 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50 and 52-57 under the written description provision of 35 U.S.C. § 112, first paragraph.

Finally, claims 89 and 90 have been rejected under 35 U.S.C. § 112, second paragraph, allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is the position of the Examiner that the recitation of “may have” renders the claim indefinite since it is unclear whether the claim in fact encompasses sequences having one amino acid substitution therein. As presently amended, claims 89 and 90 recite in relevant part: “or wherein the CKI further comprises the consensus amino acid sequences as set forth in SEQ ID NOs:37, 38 and 39, or wherein the CKI further comprises the consensus sequences set forth in SEQ ID NO:37, SEQ ID NO:38 and SEQ ID NO:39, wherein one or both of the sequences set forth in SEQ ID NOs: 37 and 39 has one amino acid substitution therein. In view of the amendments to claims 89 and 90, withdrawal of the rejection of these claims under 37 C.R.F. § 112, second paragraph is warranted.

In view of the amendments to the claims, and the foregoing remarks, the present application is believed to be in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ann R. Pokalsky". The signature is fluid and cursive, with the first name "Ann" and last name "Pokalsky" clearly distinguishable.

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